K 000388
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AUG 8 2000

Subject: Safety and Effectiveness ~~Statement~~ Summary
Clearwater Colon Hydrotherapy, Inc.
Disposable Rectal Speculum, Model SP01& SP02

The Disposable Rectal Speculum was design and constructed to the highest safety standards in regard to the injection mold and plastics used in the molding process. The mold was engineered by the finest computerized manufacturing process in manufacturer of injections mold. This process is able to give accurate and even wall thickness and sizes for each part molded to be the same as the first. Thus giving a part with smooth edges and no flash from the molding process. This prevents cutting or scraping of the client rectum or colon during the colonic process. Contour and design has been given to assure the smooth and painless insertion during colonic irrigation process.

We have chosen a plastic that meets the FDA 21 CFR 177.1520 for use in our disposable speculum. This is a proven material used by three other FDA approved manufacturers of disposable speculums. With over a million disposable speculums used since 1988 with no incident caused by the plastic or disposable speculum. This plastic is Polyethylene High Density and is made by Solvay Polymers, Inc. and is a fully tested plastic and is fully traceable.

Both the inflow hose and waste hose is a product and manufacturer which has been used by both Speciality Health Products, Inc. and Dotolo Research Inc. since 1988 in their disposable Speculum kits.

The inflow hose is manufactured by Kelcourt Plastics, Inc. 1440 N. Industrial Park Drive # 2, Nogales, Arizona 85621, Tel: (520) 281-1877
The product Alpha pvc compound was manufactured in accordance with FDA 21 Section 820 - Good Manufacturing Practices (GMP) for medical devices, as applicable to the manufacture of components, with ingredients listed in the Code of Federal Regulation 21, CFR, Section 83.2250-181.129 for use in food packaging.

The tubing produced by Kelcourt Plastics, Inc. with this material, was manufactured to the customer's specifications, using applicable GMP's with strict adherence to lot control, traceability, and cleanliness. No significant changes to the material or process have been made since the original

qualification nor will any changes be made with prior notification to the customer.

The Waste Hose is manufactured by Smooth-Bor Plastics, 2322 Del Lago Drive. Laguna Hills, CA 92653-1387, Tel: (714) 581.9530. Smooth-Bor Plastics is the producer of flexible plastic corrugated hose and tubing, which is used in a variety of applications. These application are determined by the purchaser of the tubing These applications include some medical applications, such as breathing tubes in the Respiratory Care industry. In effort to demonstrate that Smooth-Bor Plastics supports its tubing for such purposes, we submitted samples of our product to a testing laboratory for the following tests.

Cytotoxicity Study using the USP Elution Method
USP Intracutaneous Toxicity Study
USP Systemic Toxicity Study

Testing was conducted by North American Science Associates, Inc. (NAMSA), California Division.

The speculum and obturator is sealed in a separate plastic food grade bag and is then placed into another plastic food grade bag with the inflow and outflow tubing mention above.

The product is done in a clean room with particular attention paid to cleanliness and disinfected materials contact surfaces and packing equipment and materials.

These products are disinfected and are not sterile.

The above mentioned data on hoses and plastic materials is available through Clearwater Colon Hydrotherapy, Inc.

* Printed name of person required to submit 510 (k)
Mary Ruth Baker and Stuart K. Baker

* Signature of person required to submit 510(k)

Mary Ruth Baker
President

Stuart K Baker
V.P. Operations

* Title of persons submitting 510(k)

President and V.P. Operations

* Name of Company
Clearwater Colon Hydrotherapy, Inc.

* Date
January 31, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 2000

Mr. Stuart K. Baker
ClearWater Colon Hydrotherapy, Inc.
4451-A South Pine Avenue
Ocala, FL 34480

Re: K000388
Clear Water Colon Hydrotherapy Disposable
Speculum SP01 Large & SP02 Small
Dated: June 6, 2000
Received: June 8, 2000
Regulatory Class: II
21CFR 876.5220/Procode: 78 KPL

Dear Mr. Baker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K000388

Device Name: *Disposable Speculum SP01 Large & SP02 Small*

Indications For Use:

"The indication for use of this device must be restricted to colon cleansing when medically indicated, such as before radiological or endoscopic examination."

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

n Sign-Off)
of Reproductive, Abdominal, ENT,
ological Devices
mber K000388

(Optional Format 3-10-98)

Prescription use ✓